PDUFA II
Five-Year Plan

1998 - 1999 - 2000 - 2001 - 2002

Department of Health and Human Services
FOOD AND DRUG ADMINISTRATION
Office of Management and Systems

July 1, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES Food and Drug Administration

Office of the Commissioner
Rockville MD 20857

July 1, 1998

Dear Stakeholder,

We at the Food and Drug Administration take great pride in our achievements in implementing the Prescription Drug User Fee Act of 1992 (PDUFA). With the substantial additional resources made available under that Act, significant improvements were made in the drug application review process between 1992 and 1997. During this same period, the agency reduced, by about 40%, the length of time it required to review new drug and biologic license applications, without compromising review soundness and quality.

The Agency received the prestigious Innovations in American Government Award in late 1997 for these achievements. More importantly, Congress recognized these achievements by authorizing PDUFA for five more years, through 2002, as a part of the Food and Drug Administration Modernization Act of 1997. We refer to this amended and extended Act as PDUFA II, and to the original Act as PDUFA I. PDUFA II will provide additional resources over the next five years. Those resources are provided to enable FDA to meet a new set of ambitious goals for both product development and review.

To assure that PDUFA II is at least as successful as PDUFA I, FDA initiated an intensive planning effort, challenging responsible FDA components to map out what they must accomplish over the next five years and what investments they must make each year to meet these demanding new goals. The result is this PDUFA II Five-Year Plan.

In our continuing efforts to maximize the availability and clarity of information about our review processes and plans, we are sharing this plan with all who have an interest and are making it available on the Internet (at "www.fda.gov/oc/pdufa2/5yrplan.html"). Annual adjustments to this plan are envisioned to reflect changing circumstances, including workload and fee revenue adjustments. We welcome comments, and will consider them as future adjustments are made. Comments should be addressed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852, and should refer to Docket No.98N-0495.

Michael A. Friedman, M.D.
Acting Commissioner of Food and Drugs

Executive Summary

The Prescription Drug User Fee Act of 1992 (PDUFA I) provided substantial additional resources and staffing that enabled FDA to accelerate its drug evaluation process without compromising review quality. That Act expired on September 30, 1997. However, the Food and Drug Administration Modernization Act (FDAMA) of 1997 amended PDUFA I and extended it through September 30, 2002 (PDUFA II). FDAMA also commits FDA to substantially faster review times for some applications, new goals for meetings and dispute resolution, and the transition to electronic receipt and review of applications by the year 2002.

PDUFA II authorizes FDA to collect an estimated $740 million in fees over 5 years. This plan, initiated at the direction of the Deputy Commissioner for Management and Systems, is FDA's blueprint for investing these resources. It is the product of bottom-up planning by the three FDA components directly responsible for meeting these goals: (1) the Center for Drug Evaluation and Research (CDER), (2) the Center for Biologics Evaluation and Research (CBER), and (3) the Office of Regulatory Affairs (ORA). The plan lets the centers and ORA know in advance the amount of PDUFA fees each may expect annually through 2002. This approach is a significant departure from planning under PDUFA I and should facilitate the work of CDER, CBER, and ORA in meeting the PDUFA II goals.

This plan begins with a statement of purpose, provides background information on PDUFA and the new goals, and discusses the 10 major assumptions on which the plan is based. Included is the assumption that this plan is dynamic and will be reassessed each fiscal year through 2002. The individual plans of CDER, CBER, and ORA are then summarized, followed by an overhead summary and an Agency summary.

Of the anticipated $740 million in PDUFA fees over 5 years, $456 million will be used to maintain improvements achieved in PDUFA I and to sustain the additional 659 staff-years of program effort each year that made those improvements possible. The remaining $284 million will be invested by FDA over 5 years to enable FDA to meet the new PDUFA II goals. About one-third will be spent on pay and benefits for additional human resources (325 more FTE's by 2002), one-third will support the additional staff and enhance the review process, and the remaining one-third will be spent on information technology capabilities supporting the application review process and enabling electronic receipt and review of applications.

Of the full $740 million FDA expects to collect, the distribution will be: 58 percent for pay and benefits for additional staff (983 more staff-years in 2002 than in the drug evaluation process in 1992); 10 percent for operating expense costs to support these staff and further improve the drug evaluation process; 13 percent for information technology to enable FDA to achieve the electronic submission goals and to operate more efficiently; 10 percent for overhead; 4 percent for centrally paid costs such as telecommunications and facilities; 3 percent for rental payments to the General Services Administration (GSA); and 1 percent reserved for contingencies. By organization, the distribution will be: 56 percent to CDER; 20 percent to CBER; and 6 percent to ORA. The rest is support: 10 percent for overhead; 4 percent for telecommunications, facilities, and other centrally paid items; 3 percent for rent payments to GSA; and 1 percent for contingencies.

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Purpose

This plan sets out, in broad terms, a 5-year blueprint for investing the substantial resources FDA will collect under the recently amended and extended Prescription Drug User Fee Act (PDUFA). FDA must ensure that these resources are used to meet challenging new goals associated with PDUFA. The plan will help ensure that resources are allocated to achieve these goals. This plan provides long-term assurance to the responsible FDA components about the allocation of resources expected to be available each year. Annual reviews will be conducted and adjustments will be made over time as actual changes in workload and revenues replace original estimates and as unanticipated contingencies occur and new technologies develop.

Background

PDUFA I

The Prescription Drug User Fee Act (PDUFA) of 1992 provided FDA with increasing levels of resources for the review of human drug applications. Fees that FDA collected from drug and biologic firms, 1993 through 1997, were to be used to reduce the time required to evaluate certain human drug applications without compromising review quality. Letters from the Commissioner of Food and Drugs to Congressional Committee Chairmen detailed these goals**.** By 1997, these fees were providing FDA with an additional $87.5 million a year to devote to the drug evaluation process.

FDA spent these new resources primarily to acquire personnel to review human drug applications and to update the information technology (IT) infrastructure supporting the drug review process. FDA staff dedicated to these reviews in the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Office of Regulatory Affairs (ORA) increased over 57 percent during this period--from 1,147 staff-years in 1992 before PDUFA was enacted to 1,806 staff-years by 1997. FDA has submitted annual Performance and Financial Reports to Congress on progress in streamlining the drug review process and use of the PDUFA fees.

The growing recognition of FDA's success in ensuring that these resources were well used culminated in late 1997 when FDA was awarded the prestigious Innovations in American Government Award. This award, jointly sponsored by the Ford Foundation and the Harvard University John F. Kennedy School of Government, in partnership with the Council for Excellence in Government, honored FDA's achievement in combining user fees and management principles to develop a new drug approval process that is predictable, accountable, and scientifically sound while making drugs available to the public more quickly.

PDUFA contained a "sunset" provision that caused its automatic expiration on September 30, 1997. Without further legislation, FDA would not have been able to continue to collect and spend the PDUFA fees essential to maintain the review process improvements after that date.

PDUFA II

Congress worked with the regulated industry and the Administration to ensure PDUFA's continuation. As a result, the Food and Drug Administration Modernization Act (FDAMA) was signed by President Clinton on November 21, 1997. Subtitle A of Title 1 of FDAMA amended PDUFA and extended it through September 30, 2002. This extension authorizes funds that will enable FDA to accomplish increasingly challenging goals over the next 5 years. These new goals were set forth in letters from the Secretary of Health and Human Services to Congressional Committee Chairmen on November 12, 1997. PDUFA, as amended and extended by FDAMA and with its new goals, is referred to as PDUFA II and its predecessor is now referred to as PDUFA I.

PDUFA II authorizes appropriations that will provide FDA with resources to sustain the larger drug review staff developed in the last 5 years and to achieve the even more stringent new goals.

New Goals

The new goals of PDUFA II are enormously challenging, diverse, and resource intensive. Major components of the review process will be accelerated further. Many of the goals will require the development and issuance of guidance documents. Goals are established in totally new areas, such as meetings with industry and dispute resolution. The development of infrastructure and tools necessary to move to electronic application receipt and review will also be essential. The following table provides an overview and comparison of the major goals by the end of PDUFA I and the end of PDUFA II.

Comparison of Goals at the End of PDUFA I and PDUFA II

Goal	PDUFA I	PDUFA II
Complete review of priority original new drug applications and efficacy supplements	90% in 6 months	90% in 6 months
Complete review of standard original new drug applications and efficacy supplements	90% in 12 months	90% in 10 months
Complete review of manufacturing supplements	90% in 6 months	90% in 4 months if prior approval needed
Complete review of resubmitted new drug applications	90% in 6 months	90% of class 1 in 2 months and 90% of class 2 in 6 months
Respond to industry requests for meetings	No Goal	90% within 14 days
Meet with industry within set times	No Goal	90% within 30, 60, or 75 days, depending on type of meeting
Provide industry with meeting minutes	No Goal	90% within 30 days
Communicate results of review of complete industry responses to FDA clinical holds	No Goal	90% within 30 days
Resolve major disputes appealed by industry	No Goal	90% within 30 days
Complete review of special protocols	No Goal	90% within 45 days
Electronic application receipt and review	No Goal	In place by 2002

Assumptions

Taking advantage of experience gained during PDUFA I, this plan is based on ten major assumptions. A discussion of each of these assumptions follows.

1. The program increases funded by PDUFA I will be maintained over the course of PDUFA II.

The fees collected during PDUFA I funded activities have become an integral part of FDA's resources for reviewing human drug applications. In 1997, two-thirds of these funds were spent on pay and benefits for an additional 659 Full Time Equivalents (FTE's) above the level of effort FDA was expending on the review of human drug and biologic applications in 1992. The remaining one-third of the funds were used to provide operating support, IT support, centrally funded support (for indirect costs such as utilities and telecommunications), rent, and overhead costs. The continuation of these 659 work-years of effort in the centers and ORA is crucial to FDA's ability to review drug and biologic applications rapidly. These resources are the foundation for building improvements mandated by PDUFA II.

PDUFA II ensures that these additional human resources (referred to as the PDUFA I additive base FTE's) continue to be dedicated to the drug review process over the next 5 years. They are allocated as follows:

PDUFA I Additive Base FTE's by Component

Year	CDER	CBER	ORA	Total
1998	398	187	74	659
1999 and Beyond	418	167	74	659

Adjustments in these allocations may be made if warranted by workload changes.

The 5-year estimated costs associated with these PDUFA I additive base activities are detailed in the table on the next page and reflect:

- Annual pay and benefit cost increases of 5 percent (based on 5 years' experience).
- Center support costs of $9,000 per FTE increased at 3 percent annually. These are base costs and exclude past allocations for specific projects or needs.
- ORA's support costs of $16,000 per FTE (largely due to ORA's travel costs for pre-approval inspections) increased at 3 percent annually.
- Center support cost estimates also include research support funds for CBER of $590,000 in 1998 and $295,000 in 1999 (discontinued after 1999).
- Overhead calculated as a percent of center/ORA pay and benefits (a formula prescribed by the Office of the Assistant Secretary for Finance and found reasonable by Arthur

Andersen, a major accounting firm, and validated by Inspector General audits).

- Central account and rent estimates are based on 1997 actual costs and inflated at 5 percent annually, based on experience over the past five years.

PDUFA I Additive Base Fund Estimates ($000)

Item	1998	1999	2000	2001	2002	*Total
Pay and Benefits for 659 Center/ORA FTE's	$61,366	$64,600	$67,830	$71,222	$74,783	**$339,802**
Center/ORA Support Costs	$7,021	$6,919	$6,823	$7,027	$7,238	**$35,028**
Overhead	$10,889	$11,182	$11,465	$11,862	$12,336	**$57,734**
Central Accounts	$4,230	$4,442	$4,664	$4,897	$5,142	**$23,373**
***Total**	**$83,506**	**$87,143**	**$90,782**	**$95,008**	**$99,499**	**$455,937**

*Numbers may not add due to rounding.

2. Fee revenues available to FDA will be based on annual increases of 7 percent in fee-paying applications and inflation increases of 3 percent.

During discussions leading to the enactment of PDUFA II, both industry and FDA participants focused on the largely unanticipated increase in application review workload during PDUFA I and the need to ensure increasing revenues if this trend continues in PDUFA II. The following table, derived from the Federal Register Notices FDA published each year as a part of its fee-setting process, summarizes the increasing workload.

PDUFA Application Workload Data by Year

Year	Full Application Equivalents	Percent Change from Previous Year	Allowance for Waivers or Reductions	Basis for Next Year's Fees	Percent Change from Previous Year
1993	116			116	
1994	129	11.2%	5	124	6.9%
1995	137	6.2%	6	131	5.6%
1996	157	14.6%	16	141	7.6%
1997	192	22.3%	40	152	7.8%

Based on this information, excluding 1997 data unavailable during discussions that led to PDUFA II, negotiators agreed that it was reasonable to include a workload adjustor in PDUFA II--one

that would cause FDA resources to increase or decrease as the workload fluctuated. The statute was crafted so that FDA fee revenues would increase in any year FDA receives more than 142 full application equivalents paying fees (the number that was used to set the fee level each year in the statute) and decrease if FDA receives less than 142 full application equivalents paying fees in any year.

As part of these negotiations, FDA analyzed the effect of both increasing and decreasing workload levels and inflation. Industry and FDA negotiators agreed that the most reasonable planning scenario was a continued yearly increase in fee-paying application workload of 7 percent and in inflation of 3 percent. Attachment 1 details the resource implications of these workload and inflationary increases and the fees and total fee revenue that FDA would receive through 2002 if these assumptions prevail.

PDUFA fees for 1998 were based on a workload of 152 full application equivalents, after allowing for waivers and reductions. This is 7 percent more than the 142 full application equivalents used to set the fees in the statute. For 1998, the inflation adjustment was 2.45 percent. The Federal Register Notice of December 9, 1997 (Attachment 2) documented the application of the inflation and workload adjustment factors.

These assumptions (7 percent yearly increase in fee-paying workload and 3 percent inflationary increase) are the basis of this plan--for projecting both revenues and workload. Workload changes and inflation will have to be closely monitored and adjustments made to these numbers, as warranted. Based on these assumptions, the fees that FDA expects to collect and spend each year of PDUFA II are:

Anticipated PDUFA Fee Collections by Year

Item	1998	1999	2000	2001	2002	Total
Fees Anticipated	$117,122	$132,273	$145,435	$167,168	$177,915	$739,913

Availability of these revenues will provide an unusual measure of stability to this program and enable program managers to develop realistic plans for meeting the new goals.

3. Each year FDA will spend approximately the same amount it collects in fees, maintaining adequate carryover balances at the end of each year.

If FDA spends approximately as much as it collects each year, it will use all of the PDUFA II revenues collected over the 5 years. This assumption is possible because FDA began PDUFA II with a carryover balance--the PDUFA fees FDA collected but did not obligate by the end of the fiscal year and which are "carried over" for use in a future fiscal year. At the end of 1997, the carryover cash and accounts receivable amounted to about $47.3 million. If FDA spends approximately the amount it collects each year, a similar carryover balance will continue at the end of each fiscal year. A carryover balance is necessary at the end of each year to ensure adequate operating funds in the first 4 months of each new fiscal year.

Each year, two-thirds of the PDUFA fees (product and establishment fees) are not paid to FDA until January 31--4 months after the fiscal year starts. The other one-third (application fees) is spread out over the year. For estimation purposes, this portion is distributed evenly over 12 months. These application fees in aggregate would cover FDA costs for 1⅓ months of the first 4 months of the fiscal year. FDA needs to carry forward at least 2⅔ months of operating costs into each new fiscal year to cover expenses until the product and establishment fees are received on January 31. (This concept is also discussed on pages 22-23.)

4. About $284 million will be available over 5 years for PDUFA II enhancements.

If the total amount needed to sustain the PDUFA I initiatives derived under Assumption 1 is subtracted from the total revenues FDA expects to have available each year under Assumption 2, the net available for allocation to meet the PDUFA II goals is derived. Net available is the increment available to FDA over and above the PDUFA I additive base resources already invested to support and maintain the 659 additional FTE's in the centers and ORA. This is the amount available for additional investments over the next 5 years to meet the PDUFA II goals.

Revenues Anticipated and Net Available for Allocation ($000)

Item	1998	1999	2000	2001	2002	Total
Fees Anticipated	$117,122	$132,273	$145,435	$167,168	$177,915	**$739,913**
PDUFA I Additive Base	$83,506	$87,143	$90,782	$95,008	$99,499	**$455,937**
Net Available	**$33,616**	**$45,130**	**$54,653**	**$72,160**	**$78,416**	**$283,976**

5. All statutory conditions necessary for PDUFA to operate will be met each year.

The law allows FDA access to PDUFA II revenues only if three conditions are met. This plan assumes the following statutory conditions will be met:

- FDA appropriations (exclusive of user fees) in future years must total at least as much as FDA received in 1997, with some adjustments.
- Each year FDA must spend at least as much from appropriated funds (exclusive of user fees) on the process for review of human drugs as it spent from appropriations (exclusive of user fees) on this process in 1997, with some adjustments.
- PDUFA fee revenues may be collected and spent only to the extent provided each year in FDA's appropriation.

6. Funds planned for acquiring human resources may be spent on either hiring or contracting.

To develop cost estimates, it was assumed that human resources would be acquired by hiring additional employees. The centers and ORA should not feel constrained in how necessary

additional human resources are acquired. They are encouraged to utilize contract support any time it is more practical or cost effective than hiring.

7. The amount FDA pays for rent for PDUFA and other programs will no longer be capped beginning in 1999.

For several years the congressional appropriations committees have maintained a cap on the amount of rent FDA pays the General Services Administration (GSA). The President's 1999 budget proposes to remove that cap and require FDA to pay full GSA rent charges just as other government departments and agencies do. Upon removal of the cap, the amount of rent that FDA will pay for all programs, including the human drug review process, will almost double--increasing from $46.3 million in 1998 to $88.3 million in 1999. The share of rent payable for the human drug review process will increase by $5.4 million. This plan assumes that the rent cap will be removed beginning in 1999 and that rent costs thereafter will increase for inflation (3 percent annually).

Estimated Rental Payments to GSA for PDUFA Program by Source of Funds ($000)

Rent Paid to GSA	1998	1999	2000	2001	2002
From Rent Appropriation	$6,466	$6,559	$6,704	$6,858	$7,016
From PDUFA Fees	$0	$5,428	$5,643	$5,859	$6,083
Total Rent Paid to GSA	**$6,466**	**$11,987**	**$12,347**	**$12,717**	**$13,099**

Should this assumption prove incorrect, the amounts planned for increased rent costs will be transferred to the contingency reserve (Assumption 8).

8. A small but increasing amount will be held in a contingency reserve each year after 1999.

The likelihood that unanticipated events will occur increases each succeeding year of the plan. To cope with these events, a small but increasing amount will be held in a contingency reserve each year after 1999. One such contingency is utility costs that FDA did not have to pay in 1997 and earlier but may have to pay in the future. However, these contingency reserves are being kept to a minimum in order to allocate as much of the planned revenue to the centers and ORA as possible to implement their plans. All funds anticipated during 1998 and 1999 are allocated in the plan.

Contingency reserves of $1 million, $2 million, and $5 million are planned for fiscal years 2000, 2001, and 2002, respectively. In addition, if GSA rent remains capped in 1999 or later years, funds planned for GSA rent increases will be added to the contingency reserve. Potential claims on this reserve will be assessed in the second quarter of each fiscal year and allocations will be

made by the end of the second quarter. Funds not required for contingencies will then be allocated among CDER, CBER, and ORA for PDUFA needs.

9. Total PDUFA funding from appropriations and fees should increase by almost 45 percent over the course of PDUFA II.

The above assumptions permit a projection of revenues available for the review of human drug applications through 2002. The revenues resulting from PDUFA II will allow program funding to increase by over 45 percent over the 5 years of this program--from $232 million in 1997 to $338 million in 2002. Although large, this increase is less than the compounded increase in workload (7 percent) and inflation (3 percent) that forms the basis of these revenue projections. Workload and inflation increases alone, when compounded, exceed 55 percent over 5 years.

This PDUFA II 5-year plan is based on the total revenue stream shown in the table below. These funds can be invested for maximum security in addressing the challenges of the new goals and the growing workload.

Projection of Funds Available for the Human Drug Application Review Process ($000)

Source of Funds	1997 Actual	1998 Estimate	1999 Estimate	2000 Estimate	2001 Estimate	2002 Estimate
S&E Appropriations	$141,493	$141,493	$143,525	$146,682	$150,056	$153,507
Rent Appropriations	$6,466	$6,466	$6,559	$6,704	$6,858	$7,016
Fees from Industry	$84,289	$117,122	$132,273	$145,435	$167,168	$177,915
***Total Funds**	**$232,249**	**$265,081**	**$282,357**	**$298,821**	**$324,082**	**$338,438**

*Numbers may not add due to rounding.

10. The plan will be reassessed and revised annually.

All allocations in the plan are subject to review and reassessment early in each fiscal year as figures for workload and revenue for the previous year are available and better estimates for the next year's revenues are made. Of course, adjustments will have to be made based on these assessments. But the plan will continue to have value as the baseline from which future changes will be made. This annual reassessment process is discussed further on page 26.

Plans

The planning process for meeting new PDUFA II goals began during discussions with industry in the last year of PDUFA I. As new goals were proposed, resource implications were also estimated and discussed. These ongoing discussions over many months resulted in the new goal letters of November 12, 1997 and the PDUFA II resource levels and adjustors to achieve the goals were enacted in the statute.

Less than a month after President Clinton signed FDAMA, the Deputy Commissioner for Management and Systems allocated the first round of PDUFA II resources. He asked CDER, CBER, and ORA to develop individual 5-year plans detailing resources needed over the course of PDUFA II. These organizations were also asked to work together on specific plans and milestones for achieving paperless application receipt and evaluation.

The Office of Management and Systems (OMS) worked closely with CDER, CBER, and ORA to integrate their plans into an overall FDA plan. The primary focus of this effort was to ensure sound plans supporting PDUFA II goals. An analysis of the IT portions of each component's plan is contained in a separate PDUFA II Information Management Five-Year Plan (Attachment 3). That plan identifies the final IT amounts planned and the rationale. It also outlines the process for releasing funds held in reserve, the process for securing funds for projects not credentialed by FDA's Technical Review Board, and general instructions regarding performance reviews and clearance procedures.

The overall plan resulting from this process provides a sound framework for the investments needed to ensure FDA success with PDUFA II. The following pages summarize the planned distribution of PDUFA II funds to each component (CDER, CBER, and ORA) over the next 5 years and ends with an FDA Plan Summary. The two largest demands will be: (1) additional human resources to meet the more stringent application review times under PDUFA II goals and (2) IT investments to achieve paperless application receipt and review by the end of PDUFA II.

CDER Plan Summary

CDER developed a detailed overall plan for the 5 years of PDUFA II. It is supported by individual plans and estimates from various CDER components. The plan, after discussion and adjustments agreed to by CDER, would require an additional $163.8 million over 5 years. The tables on page 13 present a year-by-year resource summary with three principal components: (1) personnel and support, (2) review process enhancements, and (3) information technology.

Personnel and Support

The largest portion of CDER's request is for funds to hire and support additional staff for the drug evaluation process. This represents $91.4 million (56 percent) of CDER's total plan. CDER would be able to add 240 more FTE's to the drug review process by 2002. This number is in addition to the PDUFA I additive base of 418 FTE's and CDER's appropriated PDUFA base of 749 FTE's--for a total PDUFA effort of 1407 FTE's by 2002.

CDER developed an algorithm to estimate its staffing needs for its largest review component--the Office of Review Management (ORM)--over the 5 years of PDUFA II. The PDUFA work units completed and FTE's utilized in 1997 were used to calculate work units processed per FTE. Work units for 2002 were then estimated using projected growth in each submission category based on experience over the past 5 years. Weighting factors for each submission category were included to account for the increased PDUFA II goals. These growth and weighting factors, along with PDUFA II goals, were analyzed in ORM senior staff meetings and adjustments were made as a result.

The estimated work units for 2002 were then calculated using these growth and weighting factors. The results were divided by the 1997 work units per FTE to estimate the total PDUFA FTE's needed. The current PDUFA FTE ceiling was subtracted to determine the additional number of FTE's needed by 2002. This methodology supports the 147 additional FTE's requested for ORM. The increase of 60 FTE's for the Office of Pharmaceutical Sciences (OPS), which is responsible for the chemistry and pharmacology reviews, is based on the ORM increase. Increases for the other components, totaling 33 FTE's, were based on specific needs of each component to support the achievement of PDUFA II goals.

After discussions with CDER, it was agreed that the 1998 FTE increase would be limited to an additional 23 for the non-ORM and non-OPS components of CDER (supported by 3 months payroll, assuming an average "on-board" date of July 1). Substantial increments are provided for ORM and OPS in 1999.

The Personnel and Support subtotal also includes funds to acquire more space for this additional staff--$3.8 million over the 5 years. This amount will probably be used to pay increased space rental costs to GSA and will be held in reserve until arrangements are made for acquisition of this additional space.

Review Process Enhancements

The second component of CDER's plan is funding for a number of enhancements to the application review process. CDER plans $11.9 million (7 percent of the total plan) for this purpose. These improvements span many offices which directly contribute to or support the attainment of PDUFA II goals. It includes funds to: standardize and improve review practices, expedite the validation of methods in new drug applications, train reviewers, increase clinical trial inspections, and improve PDUFA time reporting systems. Also included are estimated travel funds for International Conference on Harmonization (ICH) meetings that will promote accelerated drug development through agreements on shared standards for use in the United States, Japan, and European pharmaceutical authorities. The actual distribution of these funds will be decided each year by the Office of External Affairs which coordinates ICH activities.

Information Technology

The final component of CDER's plan is $60.7 million (37 percent of the total) for IT enhancements for the drug approval process and includes three parts: (1) funds to develop the capability for electronic application receipt and review by FY 2002 account for $19.7 million; (2) funds for replacing CDER's management information system account for $9 million, plus another $3 million held in reserve; and, (3) funds for many other IT enhancements that support the PDUFA II goals (such as replacement of one-third of the personal computers of the reviewers every 3 years and overall maintenance and upgrading of CDER's data systems and networks that support PDUFA) account for $21.5 million over 5 years, plus another $3.4 million in reserve. The CDER IT reserve also includes another $3 million that is tentative, pending further discussion with FDA's Office of the Chief Information Officer (OCIO).

The IT part of the plan was compared to industry practices and standards utilizing outside contract support. As a result, some adjustments were made and other amounts are held in reserve until more complete plans for their use are agreed to between CDER and the OCIO. The OCIO will advise CDER on how funds held in reserve can be released and any other clearance processes for planned funds for IT projects.

The table at the bottom of the following page summarizes the total PDUFA funds added to CDER each year. The first three lines show the amounts to support the PDUFA I additive base funds. The fourth line shows the total PDUFA II plan request and the last line shows the total of the PDUFA fee revenues planned for CDER each year.

CDER Plan Summary Tables--PDUFA II

in Addition to PDUFA I Additive Base ($000)

Note: Numbers Are Rounded and May Not Add

Category		1998	1999	2000	2001	2002	5-Year Total
PDUFA I Additive Base FTE's		398	418	418	418	418	
Total Additive PDUFA FTE's in This Pla	(1)	421	556	591	626	658	
Additional FTE's Planned		23	138	173	208	240	
(Increment Each Year)		23	115	35	35	32	
Salary and Benefits for Additional FTE's	(2)	$490	$12,350	$16,256	$20,522	$24,863	$74,480
Operating Support for Additional FTE's	(3)	$207	$1,279	$1,652	$2,046	$2,431	$7,615
Startup Costs for New FTE's (One-time	(4)	$219	$1,093	$333	$333	$304	$2,280
Recruitment/Relocation/Renos/Security		$1,221	$550	$500	$500	$500	$3,271
OMS Reserve for Additional Space			$690	$865	$1,040	$1,200	$3,795
Subtotal--Personnel and Support		**$2,137**	**$15,961**	**$19,605**	**$24,440**	**$29,298**	**$91,441**
ICH Support	(5)	$420	$420	$420	$420	$420	$2,100
Redesign of Scientific Review Process		$3,392	$1,536	$1,747	$1,560	$1,581	$9,816
Subtotal--Process Enhancements		**$3,812**	**$1,956**	**$2,167**	**$1,980**	**$2,001**	**$11,916**
Electronic Submissions		$4,979	$4,897	$4,371	$2,780	$2,660	$19,687
Document Management		$1,772	$2,847	$2,073	$1,176	$1,177	$9,045
Other Electronic Initiatives	(6)	$4,998	$4,750	$4,748	$3,503	$3,544	$21,543
Reserve Pending OIRM Approval	(7)	$939	$2,845	$2,894	$1,860	$1,850	$10,388
Subtotal--Information Technology		**$12,688**	**$15,339**	**$14,086**	**$9,319**	**$9,231**	**$60,663**
Total Plan		**$18,637**	**$33,256**	**$35,858**	**$35,739**	**$40,530**	**$164,020**

(1) PDUFA Additive Base FTE's (preceeding line) plus Additional FTE's Planned.
(2) Salary and benefits estimated at $85,228 in 1998 and escalated at 5% annually thereafter. The 1998 amount is reduced by 75% for a July 1 estimated on-board date.
(3) Operating Support per FTE at $9,000 per year and inflated at 3% annually beginning in 1999.
(4) $9,500 per FTE is added only once, in first year the FTE is provided, for start-up costs.
(5) Estimate only: actual distribution of ICH funds will be decided each year by the Office of External Affairs.
(6) Includes $780,000 for enhancing either CDER or ORA automated system for reporting inspection resullts.
(7) Funds in this line include $900,000 for integration with ORA systems. Reserves will be released after FDA Chief Information Officer (CIO) has approved uses. $3 million of these reserves is tentative pending discussions with the CIO.

Total Additive PDUFA Funds for CDER--Base and Plan ($000)

Note: Numbers Are Rounded and May Not Add

Category	1998	1999	2000	2001	2002	5-Year Total
Base Payroll for 418 FTE's (5% Inflatio	* $40,517	$44,333	$46,549	$48,877	$51,321	$231,596
Base Operating Funds (3% Inflation)	$3,582	$3,875	$3,991	$4,111	$4,234	$19,793
Subtotal--Base Allottment	$44,099	$48,207	$50,540	$52,988	$55,555	$251,389
Total for PDUFA II Five-Year Plan	$18,637	$33,256	$35,858	$35,739	$40,530	$164,020
Total PDUFA Additive Funds--CDER	**$62,736**	**$81,464**	**$86,398**	**$88,726**	**$96,085**	**$415,409**

* Payroll Base is for 398 FTE's in 1998 and 418 Each Year Thereafter (20 FTE's Transferred from CBER)

CBER Plan Summary

CBER also developed a detailed overall plan for the 5 years of PDUFA II, incorporating estimates based on information supplied by the various CBER components. This plan, after discussion and adjustments agreed to by CBER, would require an additional $59 million. A year-by-year resource summary of CBER's plan is on page 16. It has the same three principal components as the CDER plan: (1) personnel and support, (2) review process enhancements, and (3) information technology.

Personnel and Support

CBER is planning to hire and support additional staff for the drug evaluation process. This represents $19.5 million (33 percent) of their total request. This investment would enable CBER to add 57 FTE's to the application review process by 2002--in addition to its PDUFA I additive base of 167 FTE's and its PDUFA appropriated base of 292 FTE's--for a total PDUFA effort of 516 FTE's by 2002. In addition CBER will also reprogram 39 FTE's from PDUFA research work to application review work in the first 3 years of PDUFA II. Thus, the real increase in review staff is 96 FTE's (57 added with PDUFA II resources and 39 PDUFA I additive base FTE's reprogrammed into review). Considering the reprogramming of the 39 FTE's, this component would constitute about 50 percent of the CBER plan.

CBER used a different approach than CDER to develop FTE estimates. The CBER planning and budget staff used detailed information on past staff time and resources devoted to PDUFA. This information came from CBER's Resource Reporting System combined with information from discussions with senior review staff to develop estimates for additional staff needed to support each of the PDUFA II goals over the 5 years. In CBER's plan the additional FTE's needed each year were arrayed with the specific PDUFA II goals. The summary results of that analysis are found on the line labeled "Total FTE's Needed to Meet PDUFA II Goals" near the top of the first table on page 16. That total is then reduced by the 13 FTE's that CBER will reprogram from PDUFA research to review activities in each of the first 3 years of PDUFA II to arrive at the net additional FTE's needed each year.

The total funds in CBER's plan for Personnel and Support includes pay and benefits for the additional FTE's and operating costs to support them. The Personnel and Support subtotal also includes funds for acquiring space to house the additional staff--$710,000 over the 5 years. This amount will probably be used to pay increased space rental costs to GSA and will be held in reserve until arrangements are made for acquisition of this additional space.

Review Process Enhancements

The second component of CBER's plan is funding for enhancements to the application review process. CBER plans $5 million (9 percent of the total plan) for this purpose. These improvements span several offices which contribute to attaining PDUFA II goals. Included are

funds to train reviewers, increase preapproval inspections, and cost increases for CBER's Document Control Center related to increasing application volume and the transition to electronic applications. Also included are estimated travel funds for ICH meetings that will promote accelerated drug development through agreements on shared standards for use in the United States, Japan, and European pharmaceutical authorities. The actual distribution of these ICH funds will be decided each year by the Office of External Affairs which coordinates ICH activities.

Information Technology

The final component of CBER's plan is the largest--$34.4 million (58 percent of the total plan) for IT enhancements supporting the drug approval process. It has three parts: (1) funds to develop the capability for electronic application receipt and review by FY 2002 account for $9.6 million; (2) funds for replacing CBER's document tracking system with state-of-the-art capabilities account for $9.9 million; and (3) funds for many other IT enhancements that support the PDUFA II goals (such as replacement of one-third of the personal computers of the reviewers every 3 years and overall maintenance and upgrading of CBER's data systems and networks that support PDUFA) account for $10.2 million over 5 years, plus another $4.7 million held in reserve.

The IT part of the plan was compared to industry practices and standards utilizing outside contract support. As a result, some adjustments were made and other amounts are held in reserve until more complete plans for their use are agreed to between CBER and the OCIO. The OCIO will advise CBER on how funds held in reserve can be released and any other clearance processes for planned funds for IT projects.

The table at the bottom of the following page summarizes the total PDUFA funds added to CBER each year. The first three lines show the amounts to support the PDUFA I additive base funds. The fourth line shows the total PDUFA II plan request, and the last line shows the total of the PDUFA fee revenues planned for CBER each year.

CBER Plan Summary Tables--PDUFA II

Plan for Funds in Addition to PDUFA I Additive Base ($000)

Note: Numbers Are Rounded and May Not Add

Category	1998	1999	2000	2001	2002	5-Year Total
PDUFA I Additive Base FTE's	187	167	167	167	167	
Total Additive PDUFA FTE's in This Pla (1)	203	198	204	215	224	
Total FTE's Needed to Meet PDUFA II Goals	29	57	76	87	96	
FTE's Reprogrammed from Research	-13	-26	-39	-39	-39	
Net Additional FTE's Requested	**16**	**31**	**37**	**48**	**57**	
(Increment Each Year)	16	15	6	11	9	
Salary and Benefits for Additional FTE's (2)	$309	$2,517	$3,154	$4,296	$5,357	$15,633
Operating Support for Additional FTE's (3)	$144	$287	$353	$472	$577	$1,834
Startup Costs for New FTE's (One-time) (4)	$152	$143	$57	$105	$86	$542
Moves and Renovations		$200	$200	$200	$200	$800
OMS Reserve for Additional Space			$185	$240	$285	$710
Subtotal--Personnel and Support	**$605**	**$3,146**	**$3,949**	**$5,313**	**$6,505**	**$19,518**
Review Process Improvements	$976	$1,038	$875	$883	$890	$4,662
ICH (5)	$80	$80	$80	$80	$80	$400
Subtotal--Process Enhancements	**$1,056**	**$1,118**	**$955**	**$963**	**$970**	**$5,062**
Electronic Submissions	$1,453	$2,153	$1,753	$2,103	$2,103	$9,565
Document Management	$4,228	$2,359	$1,617	$917	$817	$9,938
Other Electronic Initiatives	$2,044	$2,646	$2,223	$1,744	$1,557	$10,214
Reserve Pending OIRM Approval (6)	$225	$825	$1,200	$1,175	$1,275	$4,700
Subtotal--Information Technology	**$7,950**	**$7,983**	**$6,793**	**$5,939**	**$5,752**	**$34,417**
Total Plan	**$9,611**	**$12,247**	**$11,697**	**$12,215**	**$13,227**	**$58,997**

(1) PDUFA Additive Base FTE's (preceeding line) plus Net Additional FTE's Requested (bolded line below).
(2) Salary and benefits estimated at $77,315 in 1998 and escalated at 5% annually thereafter. The 1998 amount is reduced by 75% for a July 1 estimated on-board date.
(3) Operating Support per FTE at $9,000 per year and inflated at 3% annually beginning in 1999.
(4) $9,500 per FTE is added only once, in first year the FTE is provided, for start-up costs.
(5) Estimate only: actual distribution of ICH funds will be decided each year by the Office of External Affairs.
(6) Funds in this line include $450,000 for integration with ORA systems. Reserves will be released after FDA Chief Information Officer has approved uses.

Total Additive PDUFA Funds for CBER--Base and Plan ($000)

Note: Numbers Are Rounded and May Not Add

Category	1998	1999	2000	2001	2002	5-Year Total
Base Payroll for 167 FTE's (5% Inflation *	$15,800	$14,966	$15,715	$16,500	$17,325	$80,307
Base Operating Funds (3% Inflation) **	$2,273	$1,843	$1,595	$1,642	$1,692	$9,045
Subtotal--Base Allottment	$18,073	$16,809	$17,309	$18,143	$19,017	$89,352
Total New Request	$9,611	$12,247	$11,697	$12,215	$13,227	$58,997
Total PDUFA Additive Funds--CBER	**$27,684**	**$29,057**	**$29,006**	**$30,357**	**$32,244**	**$148,349**

* Payroll Base is for 187 FTE's in 1998 and 167 each year thereafter (20 FTE Transferred to CDER).
** Operating Base is reduced by $295,000 in 1999 and 2000 as PDUFA additive research is phased out.

ORA Plan Summary

After reviewing the initial plans of CDER and CBER, ORA developed an overall plan for the 5 years of PDUFA II, reflecting resources required for the field workforce to ensure that PDUFA II goals are met. This plan, after discussion and adjustments agreed to by ORA, will require an additional $13.3 million over 5 years. The table at the top of page 19 presents a year-by-year resource summary of ORA's plan. It has the same three principal components as the center plans: (1) personnel and support, (2) review process enhancements, and (3) information technology.

Personnel and Support

ORA's plan depends on PDUFA funds for additional staff for the increasingly tight timetable for pre-approval inspections. This use represents $6.7 million (50 percent) of the total plan. This investment would enable ORA to add 28 more FTE's to the application review process by 2002 (in addition to ORA's PDUFA I additive base of 74 FTE's and its PDUFA appropriated base of 106 FTE's) for a total PDUFA effort of 208 FTE's. In 2001 and 2002, as mutual recognition agreements with the European Union become effective, some of these resources will manage international agreements rather than conduct preapproval inspections. The result is an increase of about 16 percent above ORA's current level of 180 FTE's devoted to PDUFA work. These additional staff are needed to: (1) increase preapproval inspections as the application workload grows, (2) meet the tighter review timetables for many applications mandated by PDUFA II, and (3) maintain and improve ORA's current establishment record system which will be increasingly used in lieu of custom preapproval inspections.

No increases for additional space are included in the ORA plan for Personnel and Support because the additional personnel will be deployed in locations around the country with available space. The support cost for an ORA FTE is kept at $16,000 per year (the amount allocated for an ORA FTE during PDUFA I) based on the expectation of frequent travel including international travel for preapproval inspections.

Review Process Enhancements

The second component of ORA's plan is $3.3 million (25 percent of the total plan) for enhancements to support preapproval inspection work. These enhancements include equipment, training, and time accounting. Inadequate laboratory equipment to analyze samples collected during pre-approval inspections has delayed field completion of pre-approval inspection work. For PDUFA II, ORA plans $1.3 million over 5 years to purchase specific pieces of equipment required to analyze pre-approval inspection samples. ORA is also planning on $900,000 over 5 years for PDUFA-related training. ORA's training needs are exacerbated because the 180 staff-years currently devoted to PDUFA represent time spent by over 600 different employees. Training and refresher courses for those who conduct PDUFA pre-approval inspections or analyze samples collected have to be provided for more employees than expected for 180 staff-years of work. The amount requested for training will meet this need. ORA's process

enhancement subtotal also includes $1 million to be held in reserve for work in FY 1999 to upgrade and improve its PDUFA time accounting system and to make it comparable to CDER and CBER systems. ORA's current system was designed over 25 years ago and needs to be updated. This amount will be reserved for ORA in 1999 pending better estimates of the cost of redesigning the ORA system.

Information Technology

The final component of ORA's plan is $3.3 million (25 percent of the total) to enable the field offices to receive and review electronic applications to enable field staff to prepare for pre-approval inspections. The requested funds will allow ORA to develop and update its information management infrastructure to allow paperless application processing. In addition, $1.4 million is included in the CDER and CBER requests to ensure their information systems are integrated with ORA's. CDER's plan also includes $780,000 for upgrading either CDER's or ORA's automated system for reporting inspection results; if ORA's system is chosen, then this $780,000 will also be allocated to ORA. The OCIO will send information to ORA on any other clearance processes for planned funds for IT projects.

The table at the bottom of the following page summarizes the total PDUFA funds added to ORA each year. The first three lines show the amounts to support the PDUFA I additive base funds. The fourth line shows the total PDUFA II plan request, and the last line shows the total of the PDUFA fee revenues planned for ORA each year.

ORA Plan Summary Tables--PDUFA II

in Addition to PDUFA I Additive Base ($000)

Note: Numbers Are Rounded and May Not Add

Category	1998	1999	2000	2001	2002	5-Year Total
PDUFA I Additive Base FTE's	74	74	74	74	74	
Total Additive PDUFA FTE's in This Pla (1)	74	81	88	95	102	
Additional FTE's Planned	0	7	14	21	28	
(Increment Each Year)	0	7	7	7	7	
Salary and Benefits for Additional FTE's (2)	$0	$468	$984	$1,549	$2,169	$5,170
Operating Support for Additional FTE's (3)	$0	$115	$238	$367	$504	$1,224
Startup Costs for New FTE's (One-time (4)	$0	$67	$67	$67	$67	$266
Subtotal--Personnel and Support	**$0**	**$650**	**$1,288**	**$1,983**	**$2,740**	**$6,661**
Equipment	$230	$275	$275	$275	$330	$1,385
Training	$148	$270	$175	$133	$175	$901
Reserve for Time-Accounting Study		$1,000				$1,000
Subtotal--Process Enhancements	**$378**	**$1,545**	**$450**	**$408**	**$505**	**$3,286**
Electronic Submissions	$165	$193	$313	$501	$551	$1,723
Document Management		$11	$11	$11	$21	$54
Other Electronic Initiatives	$360	$273	$261	$261	$399	$1,554
Information Technology (5)	**$525**	**$477**	**$585**	**$773**	**$971**	**$3,331**
Total Plan	**$903**	**$2,672**	**$2,323**	**$3,164**	**$4,216**	**$13,278**

(1) PDUFA Additive Base FTE's (preceeding line) plus Additional FTE's Planned.
(2) ORA pay and benefits based on 1998 estimate of $63,729 per FTE increasing at 5% annually.
(3) Operating Support per FTE at $16,000 per year and inflated at 3% annually beginning in 1999.
(4) $9,500 per FTE is added only once, in first year the FTE is provided, for start-up costs.
(5) This line does not include $900,000 in CDER plan and $450,000 in CBER plan over 5 years for integrating thier systems with ORA's. It also does not include $780,000 in CDER reserves for upgrading either CDER's or ORA's automated system for reporting inspection results, depending on which system is selected to upgrade.

Total Additive PDUFA Funds for ORA--Base and Plan ($000)

Note: Numbers Are Rounded and May Not Add

Category	1998	1999	2000	2001	2002	5-Year Total
Base Payroll for 74 FTE (5% Inflation)	$5,049	$5,301	$5,567	$5,845	$6,137	$27,899
Base Operating Funds (3% Inflation)	$1,166	$1,201	$1,237	$1,274	$1,312	$6,190
Subtotal--Base Allottment	$6,215	$6,502	$6,804	$7,119	$7,449	$34,089
Total New Request	$903	$2,672	$2,323	$3,164	$4,216	$13,278
Total PDUFA Additive Funds--ORA	**$7,118**	**$9,175**	**$9,126**	**$10,283**	**$11,665**	**$47,367**

Overhead Summary

After the plans for CDER, CBER, and ORA were developed, the Office of Management and Systems estimated the overhead costs for PDUFA II and allocations of the overhead funds. This section provides background information on how overhead is calculated, how overhead funds are used, and summarizes plans for their use in PDUFA II.

Overhead Calculation

As FDA developed PDUFA baseline costs in 1993, the Office of the Assistant Secretary for Finance prescribed the formula FDA uses to determine non-center headquarters (NCHQ) overhead costs. That formula conforms with generally accepted accounting principles and was found reasonable by Arthur Andersen consultants in subsequent annual audits. The formula is:

Total Costs of NCHQ ÷ (Salary Costs of All of FDA - NCHQ Salary Costs) = Overhead Rate

The salary costs used in this formula do not include any benefit costs. At the end of each fiscal year, the Office of Financial Management recalculates this overhead rate. To determine overhead costs attributable to the PDUFA activities, this rate is multiplied by the total PDUFA salary costs (excluding benefits) for CDER, CBER, and ORA. In 1997, FDA spent a total of $232.2 million on the drug review process as defined in PDUFA, and the 1997 PDUFA overhead costs were $23.6 million, or about 10 percent--a percent we expect to remain fairly stable through the year 2002. Agency-wide, overhead costs (NCHQ total costs) have fairly consistently amounted to about 10 percent of FDA's total costs. For 1998, the overhead for the PDUFA drug review process is estimated to be about $25.3 million.

As with all PDUFA costs, this overhead has two components: (1) a portion paid from traditional appropriations and (2) a portion paid from fees collected from industry. Under PDUFA I, the portion that must be paid from appropriations was the overhead amount FDA actually spent on this process in 1992, adjusted for cost increases since then. Under PDUFA II, that amount is further adjusted for actual costs FDA paid from appropriated funds in 1997. The adjusted overhead amount that must come from appropriations in 1998 is $14.4 million. The difference between the total estimated overhead costs of $25.3 million and the $14.4 million that must be paid from appropriated funds is $10.9 million. This is the amount of FDA's overhead costs to be paid from fees. Projections of these costs over the five years of PDUFA II are estimated in the chart below.

Projected PDUFA Overhead and Source ($000)

Source	1998	1999	2000	2001	2002
S&E Appropriations	$14,402	$14,608	$14,930	$15,273	$15,624
Fees from Industry	$10,889	$13,758	$14,809	$16,123	$17,518
Total Overhead	**$25,291**	**$28,366**	**$29,739**	**$31,396**	**$33,142**

Use of Overhead Funds

The industry fees supporting overhead will be used in two ways: (1) direct PDUFA support, and (2) indirect support. The direct support funds will pay for specific increases to support the PDUFA program. The remainder is indirect support which pays for a portion of the non-center offices that provide agency-level managerial direction and support services for all FDA programs, including PDUFA.

At the end of PDUFA I, direct overhead support funded a total of 41 FTE's at a cost of $3.3 million. These FTE's were allocated to Office of the Commissioner components whose work was directly impacted by PDUFA--such as personnel, finance, IT, facilities, contracts, and reviewing waiver requests. Over the course of PDUFA II, it is envisioned that these direct overhead FTE's will increase by 15 for a total of 56. In addition, direct overhead funds will be allotted to the OCIO for information management expenses in support of PDUFA II. OCIO will be responsible for developing and maintaining the FDA electronic gateway for the receipt of electronic PDUFA applications submitted to FDA. OCIO will also develop and implement IT standards for PDUFA-related programs and provide oversight for achieving the electronic submission goal. More information about the role and costs associated with OCIO support are provided in the PDUFA II Information Management Five-Year Plan (Attachment 3). A summary of the planned allocation of direct PDUFA overhead over the course of PDUFA II follows.

Projected PDUFA Direct Overhead ($000)

Source	1998	1999	2000	2001	2002
Direct FTE's	49	52	54	56	56
FTE Pay and Support*	$4,513	$5,394	$5,531	$5,798	$6,055
IT Support	$438	$1,447	$664	$352	$360
IT Reserves			$390	$740	$390
Total	**$4,951**	**$6,841**	**$6,586**	**$6,890**	**$6,805**

*Based on average salary and benefit cost of $72,636 in 1998 escalated at 5% beginning in 1999, and $9,000 per FTE for support costs escalated at 3% annually beginning in 1999.

FDA Summary Plan

The Agency plan for PDUFA II is a composite of plans developed by CDER, CBER, and ORA. Tables 1-7 on pages 24 and 25 summarize the overall FDA plan. The discussion below summarizes information in each of these tables.

- Table 1 shows the $456 million set aside over 5 years to maintain and support the additional staff hired under PDUFA I (referred to as the PDUFA I additive base) discussed in Assumption 1. It also shows for each year the total fee revenues expected and the amounts still available for allocation after the PDUFA I additive base funds have been subtracted from the total estimated fees available--a total of about $284 million over the 5 years.

- Table 2 shows the allocation of $290 million over 5 years, by component, planned to meet PDUFA II goals. The yearly amounts and totals for CDER, CBER, and ORA on the first three lines are from their individual plans. The next three lines show the increase in: (1) overhead, (2) central accounts, and (3) rental payments to GSA. These are necessary to accommodate the additional staff hired by the centers. The next to last line shows the reserve to be held back for contingencies in the later years of the plan (Assumption 8). The total plan allocates about $6 million more than FDA expects to collect in fees over the 5 years of PDUFA II--which is explained in the discussion of Table 4 below.

- Table 3 shows the allocation of this $290 million by expense category. About one-third of the increase will be spent for pay and benefits for 325 additional staff, one-third for IT enhancements, and one-third for other enhancements, operating expenses, overhead, rent, and contingencies. A summary of the additional FTE's planned each year above the PDUFA additive base levels on page 4 are shown below.

PDUFA II Program FTE's Above the PDUFA I Additive Base

Organization	1998	1999	2000	2001	2002
CDER	23	138	173	208	240
CBER	16	31	37	48	57
ORA		7	14	21	28
Total	**39**	**176**	**224**	**277**	**325**

- Table 4 (bottom of page 24) shows the difference between the projected fee revenues and expenditures each year and the estimated PDUFA carryover balances at the beginning and end of each year. In 1998, FDA will spend about $4.5 million less than it expects to collect but, in 1999 and 2000, this plan calls for expenditures of about $12 million and $7 million more, respectively, than expected collections. FDA can do this because it began

1998 with about $47.3 million in PDUFA carryover funds and accounts receivable. In the years 1998, 2001, and 2002, when the plan calls for FDA to spend less than it collects, the carryover balance will increase. In years 1999 and 2000, when the plan calls for FDA to spend more than it collects, these carryover balances will be utilized. This concept is reasonable and defensible considering the Agency's need to make heavier investments early in the 5 year period to meet its goals. Drawing on the carryover balances allows the Agency to plan to spend $6 million more than it expects to collect.

The table below reflects the minimum carryover balances FDA should have at the end of each fiscal year in order to begin the following year with 2⅔ months of operating funds (Assumption 3) and compares those amounts with planned carryover balances.

Estimate of Carryover Balances Needed at the End of Each Fiscal Year and Planned ($000)

Item	1998	1999	2000	2001	2002
Plan for Following Year	$144,825	$152,263	$160,033	$176,223	$185,034
Needed Year-End Carryover	$32,200	$33,900	$35,600	$39,200	$41,200
Carryover Balance in Plan	$51,579	$39,477	$32,649	$39,514	$41,207
Difference -- Needed vs. Plan	$19,379	$5,577	($2,951)	$584	$7

Carryover balances at these levels in the early years of the plan are essential in order to allow the expenditures planned in the second and third years of the plan. In aggregate, the carryover balances fall slightly below the minimum recommended level at the end of the year 2000 and are back to the minimum level in the last two years. It is likely that actual carryover balances will be higher than those shown in the plan.

- Tables 5 and 6 (page 26) summarize the allocation of the total $746 million that FDA plans to spend over the 5 years of PDUFA II (PDUFA I additive base plus increases) by component and by expense category, respectively. The last column in both tables shows the percent of total PDUFA II funds planned over the next 5 years. By component, CDER will be allocated 56 percent, CBER 20 percent, ORA 6 percent, overhead 10 percent, central accounts 4 percent, rental payments to GSA 3 percent, and contingency reserve 1 percent. By expense category, 58 percent of the total PDUFA II revenues will be dedicated to pay and benefits for staff (either contract or direct hire), 10 percent for center/ORA operating costs, 13 percent for IT initiatives, 10 percent for overhead, 4 percent for central accounts, 3 percent for rental payments to GSA, and 1 percent for the contingency reserve.

- Table 7 (page 25) summarizes the total PDUFA FTE's planned each year, showing the number of FTE's paid from the salary and expense appropriations, the number of FTE's paid from fees and considered the PDUFA I additive base, and the number of FTE's added over the course of PDUFA II under this plan.

FDA Plan Summary Tables--PDUFA II ($000)

Note: Numbers Are Rounded and May Not Add

1. PDUFA I Additive Base and Estimated Funds Available

Item\Year	1998	1999	2000	2001	2002	TOTAL	Percent
Pay and Benefits for Centers/ORA	$61,366	$64,600	$67,830	$71,222	$74,783	**$339,802**	75%
Base Operating Funds--Centers/ORA	$7,021	$6,919	$6,823	$7,027	$7,238	**$35,028**	8%
Overhead	$10,889	$11,182	$11,465	$11,862	$12,336	**$57,734**	13%
Central Accounts	$4,230	$4,442	$4,664	$4,897	$5,142	**$23,373**	5%
Total--PDUFA I Additive Base	**$83,506**	**$87,143**	**$90,782**	**$95,008**	**$99,499**	**$455,937**	**100%**
Total Estimated Fees Available	**$117,122**	**$132,273**	**$145,435**	**$167,168**	**$177,915**	**$739,913**	
Still Available for Allocation	**$33,616**	**$45,130**	**$54,653**	**$72,160**	**$78,416**	**$283,976**	

2. Planned Allocation of Available Funds--by Component

Component\Year	1998	1999	2000	2001	2002	TOTAL	Percent
CDER	$18,637	$33,256	$35,858	$35,739	$40,530	**$164,020**	57%
CBER	$9,611	$12,247	$11,697	$12,215	$13,227	**$58,997**	20%
ORA	$903	$2,672	$2,323	$3,164	$4,216	**$13,278**	5%
Overhead	$0	$2,576	$3,344	$4,261	$5,182	**$15,364**	5%
Central Accounts	$0	$1,232	$1,615	$2,057	$2,486	**$7,390**	3%
Rental Payments to GSA		$5,428	$5,643	$5,860	$6,083	**$23,014**	8%
Contingency Reserve	$0	$0	$1,000	$2,000	$5,000	**$8,000**	3%
Total Allocations	**$29,151**	**$57,412**	**$61,481**	**$65,295**	**$76,724**	**$290,062**	**100%**

3. Allocation of Available Funds--by Expense Category

Expense Category\Year	1998	1999	2000	2001	2002	Total	Percent
Pay and Benefits for Centers/ORA	$799	$15,335	$20,393	$26,367	$32,388	**$95,283**	33%
Personnel Support	$1,943	$4,423	$4,449	$5,368	$6,154	**$22,337**	8%
Process Enhancements	$5,246	$4,619	$3,572	$3,351	$3,476	**$20,264**	7%
IT	$21,163	$23,799	$21,464	$16,031	$15,954	**$98,411**	34%
Subtotal to Centers	$29,151	$48,176	$49,878	$51,117	$57,972	**$236,294**	81%
Overhead	$0	$2,576	$3,344	$4,261	$5,182	**$15,364**	5%
Central Accounts	$0	$1,232	$1,615	$2,057	$2,486	**$7,390**	3%
Rental Payments to GSA		$5,428	$5,643	$5,860	$6,083	**$23,014**	8%
Contingency Reserve		$0	$1,000	$2,000	$5,000	**$8,000**	3%
Total	**$29,151**	**$57,412**	**$61,481**	**$65,295**	**$76,724**	**$290,062**	**100%**

4. Difference Between Plan and Available, and Projected Year-End Carry-Over Balances

Category\Year	1998	1999	2000	2001	2002
Difference Between Plan & Available	$4,465	($12,282)	($6,828)	$6,865	$1,693
Est. Carry-Over Balance-Year Beginning	$47,294	$51,759	$39,477	$32,649	$39,514
Est. Carry-Over Balance-Year End	**$51,759**	**$39,477**	**$32,649**	**$39,514**	**$41,207**

FDA Plan Summary Tables--PDUFA II ($000) Continued

Note: Numbers Are Rounded and May Not Add

5. FDA Summary of all PDUFA Additive Resources--by Component

Component\Year	1998	1999	2000	2001	2002	TOTAL	Percent
CDER	$62,736	$81,464	$86,398	$88,726	$96,085	**$415,409**	56%
CBER	$27,684	$29,057	$29,006	$30,357	$32,244	**$148,349**	20%
ORA	$7,118	$9,175	$9,126	$10,283	$11,665	**$47,367**	6%
Overhead	$10,889	$13,758	$14,810	$16,123	$17,518	**$73,098**	10%
Central Accounts	$4,230	$5,674	$6,279	$6,954	$7,628	**$30,763**	4%
Rental Payments to GSA	$0	$5,428	$5,643	$5,860	$6,083	**$23,014**	3%
Contingency Reserve	$0	$0	$1,000	$2,000	$5,000	**$8,000**	1%
Total	**$112,657**	**$144,555**	**$152,263**	**$160,303**	**$176,222**	**$746,000**	**100%**

6. FDA Summary of all PDUFA Additive Resources--by Expense Category

Expense Category\Year	1998	1999	2000	2001	2002	TOTAL	Percent
Pay and Benefits for Centers/ORA	$62,165	$79,935	$88,224	$97,589	$107,172	**$435,085**	58%
Operating Funds--Excluding IT	$14,210	$15,961	$14,843	$15,747	$16,868	**$77,629**	10%
Information Technology	$21,163	$23,799	$21,464	$16,031	$15,954	**$98,411**	13%
Overhead	$10,889	$13,758	$14,810	$16,123	$17,518	**$73,098**	10%
Central Accounts	$4,230	$5,674	$6,279	$6,954	$7,628	**$30,763**	4%
Rental Payments to GSA	$0	$5,428	$5,643	$5,860	$6,083	**$23,014**	3%
Contingency Reserve	$0	$0	$1,000	$2,000	$5,000	**$8,000**	1%
Total	**$112,657**	**$144,555**	**$152,263**	**$160,303**	**$176,222**	**$746,000**	**100%**

7. FDA Summary of all PDUFA FTE's for CDER, CBER, and ORA

Expense Category\Year	1998	1999	2000	2001	2002
Base FTE's Paid from Appropriations	1,147	1,147	1,147	1,147	1,147
PDUFA I Additive Base FTE's	659	659	659	659	659
FTE's Added for PDUFA II	39	176	224	277	325
Total	**1,845**	**1,982**	**2,030**	**2,083**	**2,131**

Annual Reassessments

This plan represents a significant departure from resource planning and allocation under PDUFA I. With PDUFA II, FDA should be moving into a more predictable resource environment. This long-term plan lets the centers and ORA know at the outset the amounts each may expect each year. This early information will facilitate the work required to meet the PDUFA II goals. The plan is very aggressive with revenue assumptions based on constant workload increases. Actual workload and revenues must be monitored closely.

The plan is meant to be a dynamic framework for the investments FDA must make. It will be updated in the second quarter of each fiscal year. That update will take into account the actual accomplishments, workload, revenues, and expenses of the previous fiscal year and the planned accomplishments, workload, revenues and fees to be charged in the current year, as set out in the annual Federal Register fee adjustment notice.

If revenues are expected to be at levels lower than the assumptions of this plan, or if actual PDUFA expenditures by CDER, CBER or ORA in the previous year are significantly less than the amounts allocated, then cutbacks in hiring and other expenses will be required. On the other hand, if PDUFA revenues exceed planned amounts because workload increases at a rate greater than planned, the additional revenues will need to be allocated to cope with workload increases. Also, if unforseen contingencies do not necessitate using the contingency reserve, it will be allocated by the end of the second quarter of each year.

During PDUFA II, FDA's Office of Management and Systems will look closely at PDUFA costs and workload. If that assessment indicates that PDUFA workload is out of kilter with the distribution of resources in this plan then adjustments will be made.

Because all funds FDA expects to collect have been planned, adjustments made by the centers and ORA each year will generally be within the total amounts already planned for them each fiscal year. For example, if an unplanned IT item becomes a high priority, then cutbacks will have to be made in other components of that organization's plan (such as other IT items, hiring, or operating support) in order to fund that need. It is expected that most of the adjustments over the 5 years should fall into this category.